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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/633,445

08/01/2003

Ngoc Do

702248-99010

4687

35481

7590

08/01/2006

UPM PHARMACEUTICALS INC.  
6200 SEAFORTH STREET  
BALTIMORE, MD 21224

EXAMINER

LAO, MARIALOUISA

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/633,445

Applicant(s)

DO ET AL.

Examiner

MLouisa Lao

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/01/2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Content of Specification***

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract of the disclosure is objected to because it refers to U.S. Pat. No. 60/437,507, where it should refer to U.S. Provisional App. No. 60/437,507. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "Cushioning Beads™" in claims 1-12 is used by the claim to mean "...active-loaded beads co-processed with cushioning components under current invention..." while the accepted meaning is "placebo microspheres." The dilution of the term to encompass what the applicant intends as his invention lends confusion to one skilled in the art since the term is registered under a trademark that is intended for a specific use and meaning. One having ordinary skill in the art at the time the invention was made would interpret the term as intended by the registered trademark. The term is indefinite because the specification redefines the registered trademark term from its intended meaning.

Claims 2,3,5,6,8,9,11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "Avicel® and Ac-Di-Sol®" in claims 2,3,5,6,8,9,11 and 12 are used by the claims to represent "compactable filler and water absorbing material", while the accepted meanings and usage are well known in prior art and to an artisan skilled in the

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art. The terms are indefinite because the specification fails to show that the materials in the instant claims to be different or superior from what one with ordinary skills in the art perceive as the meaning or intended use.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 16-28 and 36-38 of copending Application No. 10/749339. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method of preparing a dosage form comprising an active cushioning agent component, which is made of the same materials as the instant claimed, and other same ingredients as the instant claimed.

Claims 1-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 16-28 and 36-38 of copending Application No. 10/749339, further in view of Mehra et al. (USPat 5,643,591) col2 lines 11-15 show that a ...” particulate blend of MCC ... about 50 microns affords a satisfactory combination of

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compression properties and dissolution characteristics...” And according to Mehra et al. in col2 lines18-22 ...”Small particle size (of the order of about 10-200 microns) is achieved by well-known techniques including crystallization, freeze-drying, and various milling processes. These can be applied to the individual components of the blend or to the dry blend itself....”

Claims 1-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims1-6 and 13-24 of copending Application No. 10/44621.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application, quite similarly, is also drawn to a method of preparing a dosage form comprising an active cushioning agent component, which is made of the same materials as the instant claimed, and other same ingredients as the instant claimed.

Thus the methods between the instant applications and the copending applications are seen to substantially overlap and they are rendered obvious to one another.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In view of the rejections to the pending claims set forth above, no claims are allowed.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Habib et al. (US5,780,055).

Habib et al. disclose a method for making cushioning beads comprising microcrystalline cellulose and a disintegrant and a tablet comprising a biologically active ingredient-loaded beads and the cushioning beads. On column 84 lines 45-48, Habib teaches "... presence of high levels of MCC in the formulation croscarmellose-containing freeze-dried beads were the most compatible producing the hardest tablets at the compression pressure ranges studied" and the ratios specifically listed in claims 7, 10, 17, 22-25. It is known in the art that MCC, microcrystalline cellulose can be in the form of Avicel PH101; whereas, Ac-Di-Sol, a disintegrant, is croscarmellose or croscarmellose sodium, which is cross-linked sodium carboxymethylcellulose. An artisan with ordinary skill in art at the time of the invention is logically motivated to use these materials as used in the pharmaceutical industry and successfully prove that these combinations will work.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khankari et al. (US 6,221,392).

The instant application claims fast dissolve tablet from a method comprising the mixture of cushioning beads with active-loaded beads.

#### *Scope of Prior Art*

Khankari et al. disclose a method for making a tablet from an active ingredient mixed into a matrix of a nondirect compression filler and a relatively high lubricant content; where the tablet dissolves rapidly in the mouth of a patient.

#### *Ascertaining the difference between prior art and the instant application*

Although Khankari et al. teach a fast dissolve tablet, it does not teach the use of cushioning beads. Yet, in col15 lines 30-54, Khankari et al. discuss the use and advantages of nondirect compression fillers and "...maximizing the quantity of rapidly dissolving, rapidly water-soluble ingredients." Khankari et al. also describe in col7 lines 47-67 and col8 lines1-13 ..." ingredients and methods for particles... include, coacervation which involves processing three mutually immiscible phases, one containing the pharmaceutical ingredient, another containing the protective coating material and a third containing a liquid vehicle... three phases are mixed... converted into a substantially solid form by crosslinking or by removal of solvent from this phase...".



*Obviousness*

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habib et al. (US5,780,055) as applied to claims 1-12 above, and further in view of Khankari et al. (US6,221,392).

The cushioning beads were taught by Habib et al. (US5,780,055) and co-processing is well known in the art, Khankari et al. (US6,221,392). It is therefore obvious to a person of ordinary skill in the art that the cushioning beads taught by Habib et al. can be used for co-processing of active-loaded beads. Further, Habib et al. (US5,780,055) in view of Khankari et al. (US6,221,392) in view of Mehra et al. (US5,643,591), in regards to the optimization of particle size of the cushioning beads as disclosed in the instant invention herein, does not render the invention novel, but obvious.

One having ordinary skills in the art at the time the invention was made would have been motivated to employ the particular instant the use of cushioning beads or to combine the active-loaded beads and the optimization of granulated mesh size particles.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the teachings of Habib et al., Khankari et al. and Mehra et al. would improve the effects of compressibility, hardness and friability of tablets and/or would produce additive characteristics to a tablet produced in said manner.

It has been held that it is prima facie case obvious to combine the teachings of the prior art in order to achieve the characteristics of the tablet of the instant application; idea of combining them flows logically from their having been individually taught in prior art. Further, one of ordinary skill in the art would have been motivated to optimize the granular size of the ingredients because the optimization step is considered well in the competence level of an ordinary skilled artisan in the pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amount of ingredients and granular size, in a composition in order to achieve a beneficial effect.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

### ***Conclusion***

Claims 1-12 are pending in the application.

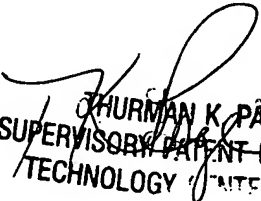
Claims 1-12 are rejected.

The Abstract is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, Ph.D. whose telephone number is 571-272-9930. The examiner can normally be reached on Monday to Friday from 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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